

### **REMARKS/ARGUMENTS**

Claims 1–13 are pending in the application. Claims 3, 4, and 10–13 have been withdrawn. Claims 1, 2, and 5–9 stand rejected.. Claims 2 and 9 are amended in this paper.

#### **I. Election/Restriction**

Applicants acknowledge that claims 3, 4, and 10–13 have been withdrawn, there allegedly being no allowable generic or linking claim. Applicants again request that if claim 1, which is generic, is allowed, that the Examiner reconsider claims 3 and 4, which are dependent from claim 1.

#### **II. Rejections Under 35 U.S.C. § 112, First Paragraph**

Claims 2 and 9 were rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The examiner alleges that these claims contain subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors had possession of the claimed invention at the time the application was filed.

Regarding claim 2, the Examiner alleges no support in the specification for using a tool to create an aperture in a silica-based substrate, stating the specification associates the patterning of silica-based substrates with etching. Applicants do not fully understand the Examiner's objection. However, it appears to Applicants that full support is provided in the specification for this claim as well as for claim 1, upon which claim 2 depends. Claim 2 recites etching an alignment structure into the first surface of the first substrate. This method step is described in the application on page 12, lines 18–27. Forming an aperture in the first substrate layer with a tool aligned with the alignment structure, as recited in claim 1, is described on page 13, lines 10–15. Thus, the specification supports using a tool to create an aperture in a silica-based substrate as well as patterning the substrate (i.e., fabricating an alignment structure) with etching.

Regarding claim 9, the Examiner alleges no disclosure to support claims directed to a process in which a capillary is inserted into an aperture in the second substrate layer in conjunction with aligning a tool with an alignment mark in the first substrate and using the tool to create an aperture in the first substrate. Claim 9 has been amended to recite a capillary element inserted into the aperture in the “first” substrate layer, rather than the “second” substrate

layer, which better claims Applicants' invention. As demonstrated below, no new matter has been added by the amendment of the claim.

The paragraph beginning at line 17 on page 12 describes fabricating a hole into a substrate, with lines 23 and 24 of that paragraph specifically describing using the hole as a junction with an external capillary. As recited in claim 8 and described, for example, on page 5, lines 10–19, on page 7, lines 23–30, on page 8, lines 4–14, and on page 12, lines 8–16, first and second substrate layers are mated together. Specifically, the passage on page 12 refers to mating the substrate layers such that a hole in the first substrate layer is positioned to correspond with a channel in the second substrate layer. The capillary element is, as described on page 12, lines 11 and 12, “completely inserted into the hole without blocking the channel...” Thus, the capillary element is inserted into the hole in the first substrate layer when the first and second substrate layers are mated; and amended claim 9 is fully supported by the disclosure.

Withdrawal of the rejection of claims 2 and 9 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement, is, therefore, respectfully requested.

### III. Rejection Under 35 U.S.C. § 112, Second Paragraph

Claim 2 was also rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. The amendment suggested by the Examiner (replacing “the” with “a”) has been implemented, thereby correcting the problem.

### IV. Rejections Under 35 U.S.C. § 103(a) as being unpatentable over Harrison et al. (US 6,224,830)

Claims 1 and 5–8 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Harrison et al. (US 6,224,830). The rejection of these claims is respectfully traversed.

To warrant rejection under 35 U.S.C. § 103(a), all the claim limitations must be taught or suggested by the prior art. See MPEP § 2142. With regard to claim 1, at a minimum, Harrison et al. do not teach fabricating an alignment structure in a surface of a first substrate layer and aligning a tool with the alignment structure.

The Examiner states on page 4 of the Office action that Harrison et al. do not teach “aligning the drill with an alignment structure in the first substrate” but asserts it would have been obvious to one skilled in the art to use an alignment structure, which the Examiner

claims is a fundamental machining technique. Applicants must respectfully disagree that it would be obvious to use this machining technique in a micromachining application. If this were the case, multiple references showing use of the technique in a micromachining arena would be readily available. Applicants are not aware of any such references, and the Examiner has not offered evidence that such references exist. The Examiner has, in effect, taken official notice that the use of an alignment structure for aligning a tool that is used to form an aperture in a substrate layer of a microfluidic device is well-known. Such official notice unsupported by documentary evidence is appropriate only where the facts asserted to be well-known are capable of “instant and unquestionable demonstration as being well-known.” See MPEP § 2144.03. Additionally, the Examiner may not make an assessment that it would be common sense to use a machining technique in a micromachining application, as an assessment of basic knowledge and common sense that is not based on any evidence in the record lacks substantial evidence support. *Zurko*, 258 F.3d 1379, 1385, 59 USPQ2d 1693, 1697 (Fed. Cir. 2001).

Even if use of the machining technique in a micromachining application were well-known, which does not appear to Applicants to be the case, Harrison et al. provide no motivation or suggestion to modify their teachings to combine them with the use of an alignment structure for aligning a tool that is used to form an aperture in a substrate layer of a microfluidic device. Applicants agree with the Examiner that one skilled in the art “would readily appreciate that the micro scale of Harrison’s channels would necessitate [very] accurate drilling.” However, nowhere do Harrison et al. acknowledge this need or teach ways of meeting the need, simply stating that the capillary should be “centered over” the channel. See, for example, column 11, lines 7–9, 59, and 60.

The only problem relating to an aperture in a substrate that is presented and solved by Harrison et al. is that of “a poor fit between the capillary outside diameter and the diameter of the hole in the plate.” The solution to this problem is not accurately drilling the hole to provide a better fit, but using a three-plate design, which allows the central plate to act as a washer to prevent glue used to seal the capillary in place from leaking down the outside edge of the capillary and into the flow channel. Harrison et al. make their recommended solution clear: “While these problems may be overcome with careful manufacturing, an alternative that is easier to manufacture is described here.” See column 11, lines 13–28.

Thus, the Harrison et al. reference neither teaches nor suggests all of the limitations of Applicants’ claim 1. Therefore, claim 1 is nonobvious. Withdrawal of the

rejection of claim 1 under U.S.C. § 103(a) as being unpatentable over Harrison et al. (US 6,224,830) is, therefore, respectfully requested. Claims 5–8 depend directly from claim 1. Any claim depending from a nonobvious claim is also nonobvious. See MPEP § 2143.03 and *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988). Therefore, dependent claims 5–8 are nonobvious. Withdrawal of the rejections of these claims is also respectfully requested.

V. Rejections Under 35 U.S.C. § 103(a) as being unpatentable over Harrison et al. (US 6,224,830) in view of Skinner et al. (US 6,605,472)

Claims 1 and 5–8 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Harrison et al. (US 6,224,830) in view of Skinner et al. (US 6,605,472). The rejection of these claims is respectfully traversed.

Applicants have demonstrated above that Harrison et al. provide no suggestion or motivation to combine their teachings with those of others to address the problem solved by Applicants. Even if such a motivation were present, combining the teachings of Harrison et al. with those of Skinner et al. would not teach or suggest all the limitations of Applicants' claim 1.

It does not appear to applicants that Skinner et al. describe a process of drilling a pilot hole that is used in the second drilling step, as described by the Examiner on page 5 of the Office action. Instead, Applicants read Skinner et al. as describing drilling a hole with a conventional conically tipped drill bit and then flattening the bottom of the drilled hole by going in again with a flat tipped drill. See column 10, lines 1–5. The diameters of the two bits appear to be the same in Figures 3a and 3b, with the second drilling step serving only to provide a flat bottom in the previously drilled hole. Thus, the aperture is already formed by the first drill bit, with the second bit merely modifying the base of the aperture. The Examiner was perhaps confused by the depiction of previously etched channel 22 in Figures 3a–c. Channel 22 is filled prior to drilling the hole and thus does not serve as a pilot hole. See column 8, lines 20–22.

Further, as described by Applicants on page 13, lines 10–12, “When a drill bit or other tool is inserted into the alignment mark, the edges of the mark prevent excessive wandering of that tool during the machining process such that the machining process is maintained within a predefined region.” Skinner et al. do not teach any such alignment structure. In column 9, lines 46–57, Skinner et al. make clear that positioning of the drill bit is “eyeballed,” with the drill being raised and the face of the chip being examined to determine if the bit is properly centered. If the hole has been started in the wrong position, the chip is removed from the drilling press,

resanded, and a new hole is started. Therefore, Skinner et al. do not teach an alignment structure formed in a surface of a substrate layer whose purpose is to align a tool in order to form an aperture in the substrate with the tool.

The combination of the Harrison et al. and Skinner et al. references neither teaches nor suggests all of the limitations of Applicants' claim 1. Thus, claim 1 is nonobvious over the combination. Withdrawal of the rejection of claim 1 under U.S.C. § 103(a) as being unpatentable over Harrison et al. (US 6,224,830) in view of Skinner et al. (US 6,605,472) is, therefore, respectfully requested. Claims 5-8 depend directly from claim 1. As any claim depending from a nonobvious claim is also nonobvious, dependent claims 5-8 are allowable as well. Withdrawal of the rejections of these claims is respectfully requested.

### Conclusion

For the foregoing reasons, Applicants believe all the pending claims are in condition for allowance and should be passed to issue. If the Examiner feels that a telephone conference would in any way expedite the prosecution of the application, please do not hesitate to call the undersigned attorney.

Respectfully submitted,



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Signed: \_\_\_\_\_

